

04-25-06

JFW

PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**TRANSMITTAL
FORM**

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

6

Application Number

10/806,515

Filing Date

March 22, 2004

First Named Inventor

Tom F. LUE

Art Unit

1646

Examiner Name

Not Yet Assigned

Attorney Docket Number

220022001610

ENCLOSURES (Check all that apply)☐ Fee Transmittal Form☐ Fee Attached☐ Amendment/Reply☐ After Final☐ Affidavits/declaration(s)☐ Extension of Time Request☐ Express Abandonment Request☒ Information Disclosure Statement
(3 pages)☐ Certified Copy of Priority
Document(s)☐ Reply to Missing Parts/
Incomplete Application☐ Reply to Missing Parts under
37 CFR 1.52 or 1.53☐ Drawing(s)☐ Licensing-related Papers☐ Petition☐ Petition to Convert to a
Provisional Application☐ Power of Attorney, Revocation
Change of Correspondence Address☐ Terminal Disclaimer☐ Request for Refund☐ CD, Number of CD(s) _____☐ Landscape Table on CD☐ After Allowance Communication
to TC☐ Appeal Communication to Board of
Appeals and Interferences☐ Appeal Communication to TC
(Appeal Notice, Brief, Reply Brief)☐ Proprietary Information☐ Status Letter☒ Other Enclosure(s) (please
Identify below):PTO/SB/08a/b Form (1 page plus
duplicate)

References (15)

Return Receipt Postcard

Remarks

CUSTOMER NO. 25225

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name

MORRISON & FOERSTER LLP

Signature

Brenda J. Wallach

Printed name

Brenda J. Wallach

Date

April 21, 2006

Reg. No.

45,193

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV 743885382 US, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: April 21, 2006Signature: *Lenay Rogus*

(Lenay Rogus)

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV 743885382 US, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

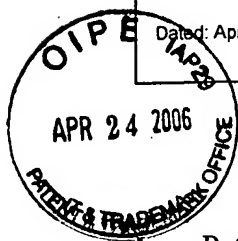
Dated: April 24, 2006

Signature: _____

(Lenny Rogers)

Patent

Docket No. 220022001610



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Tom F. LUE et al.

Serial No.: 10/806,515

Filing Date: March 22, 2004

For: METHODS AND COMPOSITIONS FOR
PREVENTING AND TREATING MALE
ERECTILE DYSFUNCTION AND
FEMALE SEXUAL AROUSAL
DISORDER

Examiner: Not Yet Assigned

Group Art Unit: 1646

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO/SB/08a/b. Copies of non-patent literature documents are submitted herewith. The Examiner is requested to make these documents of record.

This Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☐ Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☒ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☐ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
 - ☐ A fee is required. A check in the amount of __ is enclosed.
 - ☐ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above; accordingly, no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a check in the amount of __ is enclosed.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.)

Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist;

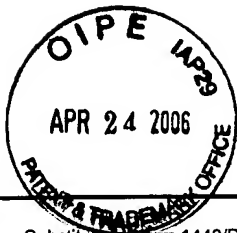
(iii) the information, protocols, results and the like reported by third parties are accurate or enabling;
or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal form is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief (such as payment of a fee under 37 C.F.R. § 1.17 (p)) is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petition and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **220022001610**.

Dated: April 21, 2006

Respectfully submitted,

By Brenda J. Wallach
Brenda J. Wallach
Registration No.: 45,193
MORRISON & FOERSTER LLP
12531 High Bluff Drive
Suite 100
San Diego, California 92130-2040
(858) 720-7961



ALTERNATIVE TO PTO/SB/08a/b (07-05)

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/806,515
				Filing Date	March 22, 2004
				First Named Inventor	Tom F. LUE
				Art Unit	1646
				Examiner Name	Not Yet Assigned
Sheet	1	of	1	Attorney Docket Number	220022001610

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	1.	US-5,770,228	06-23-1998	Edwards et al.	
	2.	US-5,770,606	06-23-1998	El-Rashidy et al.	
	3.	US-6,037,320	03-14-2000	Rosenthal	
	4.	US-2002/0032153	03-14-2002	Whitehouse	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	MM-DD-YYYY			

*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
	5.	BASKIN et al., The Journal of Urology (1999) 162:1015-1020		
	6.	BERMAN et al., The Journal of Urology (2003) 170:2333-2338		
	7.	BURNETT et al., The Journal of Urology (1997) 158:75-78		
	8.	CHATTOPADHYAY et al., Gene Therapy (2005) 12:1377-1384		
	9.	DASGUPTA et al., The Journal of Urology (2004) 171:1189-1193		
	10.	GHOLAMI et al., The Journal of Urology (2003) 169:1577-1581		
	11.	Gray's Anatomy, 38 th ed., (1999) Chapter 3: Embryology and Development, Reproductive System, pp. 210, 214-216		
	12.	MELMAN, International Journal of Impotence Research (2006) 18:19-25		
	13.	MUSICKI et al., Biology of Reproduction (2004) 70:282-289		
	14.	PESSINA et al., Endocrinology (2006) 147:61-69		
	15.	REHMAN and MELMAN, The Journal of Urology (1999) 161:200-206		
	16.	VIAGRA (sildenafil citrate) http://www.viagra.com/ web page visited April 6, 2006		
	17.	YILMAZ et al., The Journal of Urology (2002) 167:616-620		
	18.	YOON et al., International Journal of Impotence Research (2005) 17:33-38		
	19.	ZIPPE et al., International Journal of Impotence Research (2006) 18:1-18		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

sd-310399